BlueCross BlueShield Association

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August 28, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Submitted via the Federal Regulations Web Portal, http://www.regulations.gov

RE: Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 (CMS-4185-P)

Dear Administrator Verma:

The Blue Cross Blue Shield Association (BCBSA) appreciates the opportunity to provide additional comments on the Risk Adjustment Data Validation (RADV) portions of the Proposed Rule: "Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage (MA) , Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021" as issued in the Federal Register on Nov. 1, 2018 (83 Fed. Reg. 54982). We appreciate the additional time offered by the agency to submit comments on the proposals related to MA RADV audits.

BCBSA is a national federation of 36 independent, community-based and locally operated Blue Cross and Blue Shield (BCBS) companies (Plans) that collectively provide healthcare coverage for one in three Americans. For 90 years, Blue Cross and Blue Shield companies have offered quality healthcare coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare and Medicaid. Our Plans participate in MA and Medicare Part D, and many also contract with the Centers for Medicare and Medicaid Services (CMS) as Medicare Administrative Contractors.

As BCBSA noted in our previous comments, submitted on Dec. 31, 2018, we do not support the significant changes to the MA RADV audit methodology proposed by CMS in this Proposed Rule. These changes are estimated by CMS to result in a $4.5 billion potential revenue reduction to MA over the next 10 years, including $650 million in retrospective payments to the Trust Fund. As we detailed in our previous comments, BCBSA believes that the Proposed Rule relies on incomplete or improper analyses. Though BCBSA appreciates CMS' release of additional data, information and analyses to support its RADV proposal, we remain convinced that these additional analyses do not adequately support the proposal to change the methodology. Additionally, CMS' proposal to retroactively apply this flawed methodology reflects a breach of the trusted and successful public-private partnership between CMS and MA plans and would threaten the Administration's commitment to ensuring Medicare beneficiaries have access to the enhanced benefits, care coordination and financial protections provided by MA.

Our Plans are committed to accurate risk adjustment to ensure appropriate payments, and we look forward to working with CMS to develop an alternative path forward on RADV that will further this long-standing successful partnership.

Furthermore, we are aware that CMS has begun to undertake new RADV audits on a larger number of contracts in recent months, all while the final repayment methodology is yet to be determined. Some Plans that have been contacted for these audits have not yet received their final settlements from previous RADV audits. While we respect the right of the agency to audit programs that are under their jurisdiction, we believe that the "rules of the audit" or complete protocols and potential repayments should be made known before any new audits commence. This level of uncertainty is not conducive to a stable MA program.

If implemented, these proposed changes would result in unintended and unwanted consequences for MA, beneficiaries and the Medicare program at large. More specifically, this change will result in inflated audit recoveries, which would distort bidding behavior in a number of ways that are detrimental to beneficiaries. For example, higher bids result in less ability to reduce beneficiary cost-sharing and expand supplemental benefits to address social determinants. Inflated audit recoveries also discourage plan participation, deterring new entrants and constraining choice for beneficiaries. In addition, systematic underpayments due to a flawed RADV methodology would result in slowed investments in value-based care arrangements due to systemic underpayments and an increased burden on providers serving MA beneficiaries.

BCBSA recommendations are as follows:

1) **CMS should support MA stability by finalizing a RADV methodology that ends uncertainty and avoid policies that undermine the program and negatively impact beneficiaries.**
2) **CMS must apply a Fee-for-Service (FFS) Adjuster to RADV audits to ensure actuarial equivalence and accurate risk adjustment validation or determine another methodology that complies with statute.** The CMS' Study and Addendum used as the basis of the proposal does not warrant removal of the FFS Adjuster and should be withdrawn and re-evaluated.
3) **BCBSA strongly opposes the proposals to retroactively apply changes to the RADV audit methodology.** RADV methodological changes should only be applied to plan bids after a methodology is finalized. Furthermore, MA RADV audits for plan years 2011 to 2013 should be closed out with no further actions or liabilities required from the audited contracts.
4) **BCBSA urges CMS to make several significant modifications to the RADV audit methodology.** These changes include changing the criteria for the sample selection and adjustments to account for variability in order to produce statistically valid and actuarially sound results.
5) **BCBSA supports future regulatory changes to the appeals process and Hierarchical Condition Category (HCC) validation procedures that would improve the overall accuracy and fairness of the RADV audit process.**

Thank you for the opportunity to provide comments and recommendations. We would be pleased to discuss our comments with you at your convenience. Questions regarding these comments may be directed to Jane.Galvin@bcbsa.com.

Sincerely,

Kris Haltmeyer
Vice President, Legislative & Regulatory Policy
Office of Policy & Representation

Medicare Advantage Risk Adjustment Data Validation Provisions

In the Medicare Advantage (MA) Technical Proposed Rule, released Nov. 1, 2018, CMS proposed changes to the MA Risk Adjustment Data Validation (RADV) audit program. In this Proposed Rule, CMS proposes two fundamental changes to the MA RADV audit process:

1. **Removal of FFS Adjuster:** Based on the results of its FFS Adjuster study published on Oct. 26, 2018 (Study), CMS proposes to eliminate the FFS Adjuster from the RADV audit methodology. CMS also proposes that the removal of the FFS Adjuster and contractwide sampling and extrapolation methodology would apply to RADV audits already conducted for plan years 2011, 2012 and 2013 as well as for any future audits. (CMS reproduced this Study and added an addendum in June 2019).

2. **Application of Contract-Level Payment Error Rate (Extrapolation):** CMS invites renewed feedback on its methodology for calculating contract-level payment errors in RADV audits. This methodology was proposed in December 2010 and finalized in 2012. In this Proposed Rule, CMS seeks public input on the original methodology as well as other potential methodologies for sampling and extrapolation, including a subcohort approach.

BCBSA appreciates the opportunity to provide detailed comments on the RADV provisions in the Proposed Rule, which are outlined in the five key recommendation below.

Issue #1: <u>Preventing Disruption in MA</u>

The success of the Medicare Advantage market relies on accurate capitated payments to Medicare Advantage Organizations (MAOs), including stable risk adjustment and data validation policies. CMS conducts program integrity efforts in MA to prevent fraud and abuse and ensure accurate payments. CMS conducts RADV audits as part of its program integrity audits to ensure that diagnosis code data submitted by MAOs for risk adjustment purposes are supported by the appropriate medical documentation. Additionally, the stability of MA relies on preventing uncertainty for plans and other stakeholders by ensuring policies and procedures are clearly established before bids must be submitted and other activities, such as audits, are conducted.

Recommendation #1:

CMS should support MA stability by finalizing a RADV methodology that ends uncertainty and avoid policies that undermine the program and negatively impact beneficiaries.

Rationale #1:

BCBSA supports program integrity efforts in MA to prevent fraud and abuse and ensure accurate payments. Unfortunately, there has been persistent uncertainty due to lack of clarity

and transparent rule-making on RADV audits. To end this uncertainty and support the growth of MA, CMS should finalize a RADV audit methodology that is sound and ensures accurate payment.

Furthermore, as stewards of the MA program, CMS should carefully consider the proposed changes to the RADV methodology in the full context of the MA program, which is the choice of over one in three Medicare beneficiaries. Notably, CMS already accounts for actual and potential coding discrepancies under the MA program in several ways that reduce plan payments:

- Coding Intensity Adjustment: CMS applies a minimum annual across-the-board coding intensity adjustment to MA risk scores designed to account for observed differences in coding patterns completeness between the MA and FFS programs. For payment year 2019, plans are subject to a 5.91 percent reduction in risk scores due to the Coding Intensity Adjustment.
- FFS Normalization Factor: Payments to MA plans are further reduced by the FFS normalization factor, which CMS applies annually so that the average expected risk score in the applicable payment year will remain at 1.0. For example, from 2019 to 2020, CMS estimates the FFS normalization factor update will result in an average -3.08 percent change in revenue for MA plans.
- Transition from RAPS to EDS Data Files: CMS is currently transitioning between the use of data files from the Risk Adjustment Processing System (RAPS) and the Encounter Data System (EDS) to the use of only EDS data files as the sole basis for MA beneficiary risk scores. This transition has resulted in lower than expected risk scores and decreases on average in risk-adjusted revenue for plans. MA plan data reflects a median 4 percentage point difference between EDS and RAPS-based risk scores in PY 2016, resulting in further decreases in risk scores and MA plan payments.[1]
- Medical Loss Ratio: MAOs are prohibited from maintaining a Medical Loss Ratio (MLR) less than 85 percent, and MAOs that report MLR percentages lower than that threshold are required to repay the difference to CMS.

The cumulative impact of continually shifting risk adjustment and data validation processes and requirements, as well as other policies, threaten the stability of the market and could stifle plans' continued ability to modernize the program and deliver better value to beneficiaries.

Issue #2: Fee-for-Service Adjuster

A central question with the RADV audit methodology is how to address the fact that the FFS data, upon which MA payment and risk adjustment is based, is not audited. MA risk scores are constructed using a risk adjustment model with coefficients based on unaudited FFS data. Simply auditing the diagnosis codes submitted by MA plans that CMS uses to calculate HCCs and risk adjustment and then calculating an error rate against a perfect score (i.e. unaudited

[1] D. Bell et al., Milliman Report: Impact of Transition from RAPS to EDS on Medicare Advantage Risk Scores (Jan. 13, 2017), *available at*: http://careers.milliman.com/uploadedFiles/insight/2017/2370HDP_Medicare-EDS-Survey.pdf.

FFS data) does not account for the known fact that FFS data are not perfect. Thus, since MA coefficients are calibrated using unaudited FFS data, an adjustment is needed to account for the inconsistencies in the FFS data.

In its February 2012 release, CMS stated that after using the outlined methodology to calculate a preliminary payment recovery amount, CMS would then apply a FFS Adjuster before finalizing a recovery amount – effectively creating the proxy needed to accurately compare the error rates. CMS noted, "the FFS Adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims)."[2] This conclusion was supported by industry stakeholders and the American Academy of Actuaries,[3] who collectively agreed that the RADV audit methodology's determination of payment errors on the basis of validated medical records conflicts with the MA program's risk adjustment model, which is based on unaudited FFS claims. CMS stated it would conduct a, "RADV-like review of records submitted to support FFS claims data" to develop the FFS Adjuster. In the years since, stakeholders have requested public information on this review and findings related to the development of the FFS Adjuster as described in 2012.

However, in the Proposed Rule, CMS reverses its stance on the FFS Adjuster. CMS cites its Study as the primary rationale for no longer believing a FFS Adjuster is necessary.[4] CMS asserts that this analysis is the "RADV-like review" outlined in their 2012 memo.

Recommendation #1: CMS must apply a FFS Adjuster to RADV audits to ensure actuarial equivalence and accurate risk adjustment validation or determine another methodology that complies with statute.

Specifically:

a) **CMS' Study and Addendum do not warrant removal of the FFS Adjuster.**
b) **The FFS Adjuster is essential for an accurate RADV audit methodology.**
c) **CMS's proposal to remove the FFS Adjuster represents an impermissible reversal of agency position.**
d) **Only Subclause (iii) is relevant to the inclusion of a FFS Adjuster in RADV.**

Rationale #2:

a. CMS' Study and Addendum Do Not Warrant Removal of the FFS Adjuster

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[2] https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf
[3] *See* American Academy of Actuaries, Comment on RADV Sampling and Error Calculation Methodology (Jan. 21, 2011), *available at*: https://www.actuary.org/pdf/health/RADV_comment_letter_012111_final.pdf.
[4] On October 26, 2018, CMS released an Executive Summary and a Technical Appendix titled "Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits." Both of these documents are herein collectively referred to as the "Study."

In its Study and subsequent Addendum, CMS concludes that diagnosis errors in the FFS calibration data (which it refers to as the "audit miscalibration") do not lead to systematic payment error in the MA program, and, thus, a FFS Adjuster is unnecessary. However, this conclusion is based on flawed methodologies and fails to provide sufficient conclusions to permit a determination as to whether its results are reliable and reproducible. Additionally, the Study utilizes improper assumptions and data inputs and employs an analysis that is both statistically and actuarially unsound. BCBSA's analysis, as well as that of respected independent actuarial firms, have found that, in addition to not performing the "RADV-like" audit of FFS claims, the Study and Addendum contains statistical and actuarial errors that undermine its conclusions.

Below we have briefly summarized just some of flaws in the CMS FFS Study, including technical problems and faulty assumptions and conclusions. We would be happy to discuss these concerns in detail with you and your staff.

- **Failure to normalize the audited coefficients on an audited dataset:** The Study appears to use audited FFS data to calibrate new audited coefficients, but then normalizes these coefficients using *unaudited* FFS claims to calculate the final audited coefficients. This flaw leads to incorrect results. An appropriate analysis would be both calibrated and normalized with audited FFS claims data to ensure accurate comparison.

- **Inconsistent comparison data:** The MA RADV audit methodology involves the random sampling of *beneficiaries* who satisfy specified criteria. By contrast, the Study is based on *claims*, rather than complete member profiles, which were pieced together from three distinct data sets. These claims represent only outpatient services and do not represent a complete set of services. CMS does not identify all of the criteria it used to create its sample or whether these claims were selected at random. Furthermore, the claims the Study used predate CMS' recalibration of the HCC model in 2013 and fail to capture or discuss the impact of the phase in from ICD-9 to ICD-10 diagnosis coding or the phase-in of encounter data as a diagnosis source.

- **Conversion of claim error rate to beneficiary error rate:** CMS inappropriately makes the assumption that HCC claim error rates are statistically independent and, thus, can be raised to the power of the average number of claims per beneficiary to calculate the beneficiary HCC error rate. Due to normal provider coding practices, claim error rates will not be independent. The beneficiary error rate is greatly understated due to this assumption. CMS should have directly calculated a beneficiary error rate using all claims for a beneficiary for determining the FFS Adjuster. In addition, CMS inappropriately used the mean of claim volumes per enrollee to estimate beneficiary-level error rates that might result from their sampled claim-level error rates. However, BCBSA concludes it is not correct to assume that all audited members would have an average volume of claims due to the fact that within any patient population, beneficiaries will have a wide range of claims within a calendar year. As claim volume increase, the likelihood of a validation error shrinks significantly. Conversely, for beneficiaries with low claim volumes, the beneficiary-level error rate approaches the claim-level error rate. For example, if a

beneficiary only has one claim triggering a HCC, the beneficiary-level error rate should be assumed to be equal to the claim-level error rate. As a result, the derived beneficiary-level discrepancy rates are significantly lower than what would be found if beneficiaries were audited via an appropriate "RADV-like" approach.

- **Randomly removing HCCs introduces errors:** CMS' analysis simulates an audit of FFS data by randomly determining when to remove particular HCCs from particular members in the FFS Medicare data set, thus treating as irrelevant the differences in expected claims' costs associated with beneficiaries who have substantiated HCCs and those who do not**.** This assumption is flawed since it means that the analysis is as likely to remove the condition from a person with high health costs as a person with low health costs, when, in reality, it is more likely that the person with lower health costs would have an unsubstantiated diagnosis.

- **The Study uses an inappropriately small sample size:** The data set used for discrepancy analysis was a very small sample size, resulting in low to no credibility for many HCCs. The analysis attempted to adjust for this by using averages for those HCCs without credibility. We believe that an accurate assessment cannot be made by simply using averages.

- **Flawed assumption conflating payment error and error in recoveries:** CMS contends that any issues with a certain HCC due to unaudited FFS input data are smoothed out across the entire HCC model. This does not translate to eliminating the need for a FFS Adjuster when comparing MA error rates with FFS error rates for the purpose of recoveries – these are independent issues.

b. The FFS Adjuster is Essential for an Accurate RADV Audit Methodology

In the February 2012 release, CMS announced plans to develop a FFS Adjuster that would apply to its RADV audits. While committing to develop the FFS Adjuster,[5] CMS noted that "[t]he actual amount of the adjuster will be calculated by CMS based on a RADV-like review of records submitted to support FFS claims data."[6] Therefore, the FFS Adjuster was essential to calculate a permissible level of payment error and limit RADV recoveries to payment errors in excess of that level. The absence of a FFS Adjuster when making RADV payment error recoveries would lead to systematic MA plan underpayments, in violation of the Social Security Act's (SSA's) mandate for "actuarial equivalence." 42 U.S.C. § 1395w-23(a)(1)(C)(i). Since the

[5] CMS has repeatedly acknowledged data inconsistency concerns in reference to the FFS Adjuster. *See, e.g.*, CMS, Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract (Feb. 24, 2012) ("Payment recovery amounts will be subject to a fee-for-service adjuster. The fee for service adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract's payment error is different from the documentation standard used to develop the Part C risk-adjustment model."); CMS5881, "Model Calibration Factor," at p.6. ("In RADV audits, we expect coding perfection from MA plans . . . [but] [i]n FFS Medicare, some portion of diagnoses on FFS claims are not documented in medical record[s] . . . . Under RADV, plans are being held to a different (higher) standard for diagnoses.")

[6] https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf

2012 release, MA stakeholders have repeatedly requested the public release of the FFS Adjuster as well as the data and analysis CMS used to calculate the FFS Adjuster.

However, in the Proposed Rule and accompanying Study, CMS contends that diagnosis errors in FFS claims data do not create systematic payment errors, and that, even if they did, it would be inappropriate to correct for this problem through payment adjustments applied to audited contracts. As mentioned above, CMS contends it may not matter if a MA HCC coefficient is allocated an inflated value because such an error may balance out with the remaining HCCs and demographic coefficients relative to the benchmark average costs. However, in the context of a RADV audit recovery, CMS is holding MA plans liable for any and all coding errors (i.e., 0 percent error rate standard) while using a significant error rate to create the values associated with the diagnosis codes targeted in the audit. The application of a FFS Adjustor to RADV recoveries is necessary to cure the impact of FFS errors on the values attributed to codes (and related coefficients) found in error that are then extrapolated to the entire MA contract. Consequently, without a FFS Adjuster, audited MA plans would be unfairly penalized by incurring inflated recoveries that ultimately stem from miscalibrated coefficients.

The unique characteristics of the CMS-HCC risk adjustment model calibration and the RADV audit methodology combine to create a fundamental flaw in the calculation of RADV audit recoveries. CMS creates disease coefficients based on unaudited FFS data—which, even if they potentially balance out in terms of calculating original payments to MA plans—necessarily lead to inflated calculations of RADV recoveries, thereby penalizing MA plans. During RADV audits, CMS unfairly holds MA plans to a perfect (i.e., 0 percent) error rate standard, despite the fact that a significant error rate in the FFS data associated with a specific disease will impact the MA plan's contract-level extrapolated recoveries. In addition, payments to MA plans are already reduced by the coding intensity adjustment as previously discussed, which accounts for differences in coding completeness between FFS and MA.

BCBSA again concludes that the application of the FFS Adjuster is necessary to ensure proper RADV audit recoveries and prevent the sort of systematic errors that would otherwise result. CMS is required by law to ensure that MA plans are compensated at a level that is actuarially equivalent to FFS. Evaluating the results from a RADV audit using HCC coefficients based on an unaudited dataset is not actuarially equivalent as required by law. While this issue is overlooked in the Proposed Rule and accompanying Study, BCBSA recommends that future rule-making on RADV audits must address this critical shortcoming. To remedy this problem, CMS must preserve the FFS Adjuster or entirely reformulate the CMS-HCC risk adjustment model and RADV audit methodology.

c. CMS's Proposal to Remove the FFS Adjuster Represents an Impermissible Reversal of Agency Position

BCBSA urges CMS to reconsider its proposal to eliminate the FFS Adjuster. In the meantime, CMS has not engaged in the steps necessary and sufficient to properly effectuate its reversal in agency position. In the absence of any adequate justification, the regulatory implementation of CMS' proposed new policy position would be arbitrary and capricious.

As noted above, the Proposed Rule and Study do not address the underlying data inconsistency issue that led to CMS' adoption of the FFS Adjuster. CMS' failure to address this issue is surprising given that it is statutorily required to comply with the SSA's "actuarial equivalent" and "same methodology" requirements. Indeed, CMS fails to fully address its policy positions and related issues, not simply with respect to the FFS Adjuster, but also in regards to several of the RADV issues mentioned in the Proposed Rule. The background information and agency has provided is incomplete and unclear, and stakeholders are frustrated in attempts to provide productive comments.

CMS' efforts to explain its departure from prior policy regarding the FFS Adjuster are primarily dependent upon its Study, which for the reasons noted above, is clearly deficient. The subsequently released data and addendum were also not sufficient. Abandoning its prior commitment to conduct a "RADV-like audit" to determine the amount of the FFS Adjuster, CMS, instead, undertook an analysis BCBSA believes is actuarially and statistically invalid. CMS is required, at a minimum, to thoroughly support and explain its reversal in agency position and release the information needed for the public to reproduce the agency's analysis.[7] This reproduction, however, is impossible without access to the complete Study, including the underlying data and methodology.

d. Only Subclause (iii) is Relevant to the Inclusion of a FFS Adjuster

On June 28, 2019, CMS sought public comment on the extent to which 42 U.S.C. § 1395w-23(a)(1)(C) is relevant to whether CMS should include a FFS Adjuster in the RADV methodology. Subclause (i) of this provision is relevant because it establishes the actuarial equivalence requirement, which compels CMS to include a FFS Adjuster in its proposed RADV methodology. The rest of this statutory provision, however, is not relevant to CMS' decision to include a FFS Adjuster.

Subclause (ii) requires CMS to ensure risk adjustment reflects differences in coding patterns between Medicare Advantage plans and providers. CMS has implemented this provision by adopting the coding intensity adjustment, which CMS has explained is exclusively intended to address differences in the completeness of MA plan and FFS provider coding, not any differences in coding accuracy (needed for actuarial equivalence).

Subclause (iii) is also irrelevant. It provides that CMS may not use the "default risk score for new enrollees" in Special Needs Plans (SNPs) for individuals with chronic conditions, but rather "a risk score that reflects the known underlying risk profile and chronic health status." Congress adopted this provision to address the concern that if new enrollees in SNPs were given a default risk score that failed to take into account the very severe or disabling chronic conditions required to qualify for a SNP in the first place, their risk score would be too low. Furthermore, Subclause (iii) does not modify the actuarial equivalence requirement in Subclause (i) and, thus,

[7] Pub L. No. 106-554 § 515.; Office of Management and Budget, *Guidelines for Ensuring and Maximizing Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8451, 8459-60 (Feb. 22, 2002)

has no bearing on whether CMS should include a FFS Adjuster in the proposed RADV methodology.

Issue #3: <u>Retroactive Application of Proposed RADV Methodology</u>

CMS proposes to apply the new RADV audit methodology, except for the subcohort proposal, retroactively for all years after 2010, including plan years 2011, 2012 and 2013, for which RADV audits have already been conducted. CMS argues that applying this methodology reflects compliance with the Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA) as well as its fiduciary responsibility to recover funds due to the Medicare Trust Funds.

Recommendation #3:

BCBSA strongly opposes the proposals to retroactively apply changes to the RADV audit methodology. RADV methodological changes should only be applied to plan bids after a methodology is finalized. Furthermore, MA RADV audits for plan years 2011 to 2013 should be closed out with no further actions or liabilities required from the audited contracts.

Rationale #3:

BCBSA's strong opposition to applying the proposed RADV methodology to years where bids have already been submitted is compounded for plan years 2011 to 2013, for which plans have not only submitted bids, but plans have already been audited for those years. Application of the new and more expansive RADV extrapolation procedures to prior payment years would undermine the soundness of prior MA plan payments, negatively affect the applicable MA plans and the beneficiaries they serve, and undermine CMS' position as a good business partner with plans. The publication requirement in Section 1853 of the Act serves an important purpose: It ensures that MAOs have the information that they need to submit accurate bids for the following year.[8] If applied retroactively, the Proposed Rule would contravene this important objective and exceed the authority that Congress granted to CMS. Additionally, Section 1871(e) prohibits CMS from applying rules retroactively unless "retroactive application is necessary to comply with statutory requirements" or "failure to apply the change retroactively would be contrary to the public interest.[9]

Threat to Actuarial Soundness of Payments to MA Plans

During the annual MA bidding process, MAOs are required to attest to their current and projected costs to furnish coverage for eligible beneficiaries. MA plan bids must include costs associated with MA program compliance, which includes "best practices" to prepare for and

[8] 42 C.F.R. § 422.521
[9] 42 U.S.C. § 1395hh(e)(1)(A))

successfully participate in RADV audits, as well as the liability that can result from RADV audits. To this end, for most of the past seven years, MA plans and their actuaries have relied on the contract-level RADV audit methodology published by CMS in February 2012 for purposes of estimating RADV compliance costs incorporated into their annual bids.[10]

The Proposed Rule endeavors to dramatically reshape the RADV audit methodology in a manner that would increase both the probability and size of audit penalties. If applied retroactively, MA plans would be susceptible to a far greater amount of financial liability, which MA plans could not have accounted for in their prior year bids, thereby potentially rendering their prior payments actuarially unsound. In other words, the resources previously furnished to MA plans may no longer be sufficient to cover the total costs of MA plan operations and beneficiary coverage.

At no point in the Proposed Rule does CMS address the retroactive application's impact on the actuarial soundness of prior year bids. This is a significant omission given the central importance of actuarial soundness to the Medicare program and its incorporation by law into the MA program bidding process. Therefore, to properly apply its new methodology retroactively, CMS needs to explain and account for the impact to prior year bids that have already been approved.

Negative Impact on MA Beneficiaries

BCBSA further notes that under CMS' proposed methodology, projected risk scores for MAO bids would be lower, leading to higher bids, which would, in turn, result in fewer rebate dollars, higher cost-sharing and premiums, as well as benefit reductions. Extrapolation, and retroactive application of the proposed methodology would further exacerbate the fundamental problems that would stem from finalization of the proposed changes to the RADV methodology. As a consequence, MA plans would face dramatically inflated and unanticipated financial liabilities, which will have negative collateral consequences for beneficiaries and the public interest.

BCBS Plans all maintain comprehensive compliance programs dedicated to meeting MA requirements. Increasing the risk associated with RADV audits will necessarily divert resources away from innovations that improve beneficiary care and towards compliance activities. To sustain these increased efforts, Plans must receive clear and adequate notice of applicable legal and operational requirements to ensure the delivery of high-quality care to beneficiaries.[11]

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[10] CMS, Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits (Feb. 24, 2012), *available at*: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf

[11] For example, in its FY 2018 Financial Report, which is based on data through June of 2017, HHS calculated an average gross payment error rate of 8.10 percent and an average net payment error rate of only 1.37 percent. This reflected a marked improvement from FY 2016 results, which calculated an average gross payment error rate of 9.99 percent and average net payment error rate of 4.19 percent. *Compare* HHS, Fiscal Year 2018, Agency Financial Report (Nov. 2018), at pp. 207-208, *available at*: https://www.hhs.gov/sites/default/files/fy-2018-hhs-agency-financial-

However, CMS has taken a sudden change in direction regarding the FFS Adjuster, the elimination of which will force MA plans to comply with a potentially higher error and documentation standard than that applied in the FFS. Even if applied prospectively, the negative ramifications of this reversal, as exponentially increased through extrapolation, would be substantial. If the proposed retroactive approach were implemented, MA plans would also be held to a more stringent standard for a multi-year period that preceded the existence of that standard. This result would be unfair for MA plans. Further, because only a small number of randomly selected plan contracts were audited in the 2011 to 2013 time period, those plans would unfairly bear the full negative effect of this reversal in policy.

Finally, the increase in MA plan liabilities that would flow from the Proposed Rule's RADV methodology may deter future MA program participation. Those plans that choose to participate will be forced to reserve a greater portion of their revenue to account for expanded and retroactively-applied RADV audit liabilities. To accommodate these increased reserve needs, a MA plan may be forced to:

- Decrease supplemental benefits to their beneficiaries
- Increase beneficiary cost-sharing amounts and premiums
- Reduce resources for the development of new value-based payment models
- Decrease their provider networks
- Offer fewer benefit packages for beneficiaries

Thus, the ultimate harm stemming from the new methodology would impact not simply MA plans, but also their beneficiaries and the Medicare program as a whole.

BCBSA believes that the negative repercussions for retroactive application of the revamped RADV methodology to both MA plans and beneficiaries are significant. Nonetheless, CMS does not address these concerns in the preamble to the Proposed Rule. When referencing the public interest, CMS only cites the agency's objective to obtain greater recoupments from audited plans, without recognizing that the overwhelming portion of MA plan payments are devoted to furnishing MA coverage and benefits. By contrast, BCBSA believes that the public interest is best served by a robust MA program, which offers beneficiaries a variety of plans and benefit packages, and that retroactive application of the RADV audit methodology hinders rather than promotes this interest.

Therefore, because any potential benefits garnered by audit recoupments would be substantially outweighed by the negative effects to MA plans and beneficiaries, BCBSA also contends that CMS lacks statutory authority to retroactively apply the proposed RADV methodology. The public interest would be especially harmed by retroactive application to

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report.pdf *with* HHS, Fiscal Year 2016, Agency Financial Report (Nov. 2016), at pp. 213-214, *available at*: https://www.hhs.gov/sites/default/files/fy-2016-hhs-agency-financial-report.pdf.

payment years 2011 through 2013, during which time MA plans were already subject to RADV audits. By applying the new methodology to RADV audits to years when audits have already been completed, CMS would be imposing unforeseen financial liabilities on MA plans, thereby, exacerbating collateral effects to the MA program and beneficiaries.

Issue #4: <u>Proposed RADV Methodology</u>

In its December 2010 memo, CMS proposed a RADV audit methodology that it purported would be a statistically valid sample of beneficiaries from each audited MA contract and then an extrapolation from the results of that sample audit would be used to calculate a contract-level payment adjustment.[12] As CMS stated, though this methodology was described as final in 2012, it was never implemented – audits for payment years 2011, 2012 and 2013 have been conducted according to this methodology, but contract-level recoveries have not yet been collected. CMS is again asking for comment on this issue. In the Proposed Rule, CMS stated that, in addition to the "final" methodology from 2012, it has identified other potential methodologies for sampling and extrapolation. Specifically, CMS contemplates a "subcohort" audit methodology where the calculation of improper payments would be made on the audited MA contract for a particular subcohort or subcohorts of enrollees in a given payment year. CMS asks for comment on both the contract-level audit methodology published in February 2012 and the new proposal for an extrapolated audit methodology based on subcohorts of enrollees. CMS also seeks comment on whether there are particular situations when one of these methodologies might be preferable to the other. Finally, CMS indicates that it intends to apply the finalized RADV payment error methodology or methodologies to payment year 2011 and all subsequent years, but seeks comments on whether the agency should revise the contract-level audits that have already been conducted, but not finalized, for payment years 2011, 2012 and 2013.

Recommendation #4:

BCBSA urges CMS to make several significant modifications to the RADV audit methodology related to sample selection and substantiation in order to produce statistically valid and actuarially sound results.

Specifically:

a) **CMS should remove the criteria that a "RADV-eligible" beneficiary has at least one HCC for the applicable payment year.**
b) **CMS should adjust the audit methodology to account for variability among HCC-specific substantiation rates, but not finalize its policy to adopt the subcohort approach until further detail is provided.**

[12] "Medicare Advantage Risk Adjustment Data Validation Notice of Payment Error Calculation Methodology for Part C Organizations Selected for RADV Audit – Request for Comment."

Rationale #4:

While CMS suggests that it is not required by law to describe its RADV methodology through a formal regulatory process, there is no debate within stakeholders that RADV audits must employ valid sampling and extrapolation methods. To that end, BCBSA is providing comments to ensure that the RADV audit methodology, in addition to incorporating an appropriate FFS Adjuster, employs sampling and extrapolation methodologies that ensure actuarial equivalence and prevent unintended consequences. BCBSA believes that certain aspects of CMS' contract-level audit methodology, which were incompletely described in the agency's five page February 2012 publication and revisited in the Proposed Rule with additional approaches, undermine its overall statistical and actuarial soundness. Many of these shortcomings were detailed in a July 2018 report published by the Wakely Consulting Group, which revealed that CMS' contract-level audit methodology will lead to inequitable treatment of MA plans due to characteristics unrelated to coding accuracy.[13] The report describes simulations that reflected a high degree of randomness among outcomes, even for contracts with identical error rates, and large sensitivities to small variations in diagnostic mix.

Furthermore, CMS does not provide adequate detail of its proposal to conduct RADV audits of certain patient subcohorts for BCBSA to be able to provide substantive comments at this time. We urge CMS not to proceed with this proposal until adequate information and analysis is released and stakeholders are able to provide actionable feedback.

a. Sample Selection – "RADV-Eligible" Members

BCBSA disagrees with the methodology's use of a "RADV-eligible" criteria that includes a requirement that a beneficiary have at least one diagnosis code that resulted in an assigned HCC for the applicable payment year, which biases the sample payment error rate upwards. This distortion results in an inaccurate error rate across the entire contract (RADV-eligible and non-eligible). In contrast to the other five selection criteria, which are designed to include fully participating beneficiaries in an applicable MA contract while excluding outlier beneficiaries (i.e., beneficiaries with End Stage Renal Disease (ESRD) and hospice status), the justification for excluding beneficiaries who lack an assigned HCC is not readily apparent.

b. Variability among HCC-Specific Substantiation Rates

CMS' proposed methodology should consider the fact that certain HCCs are more difficult to substantiate in documentation in a given medical record. CMS noted that "there are attributes intrinsic to a specific HCC that drive measurement errors higher or lower. For example, some underlying diseases may be more difficult to evaluate and therefore the discrepancy rate or

[13] Wakely Consulting Group, *Medicare RADV: Review of CMS Sampling and Extrapolation Methodology* (July 2018), *available at*: https://www.ahip.org/wp-content/uploads/2018/07/Wakely-Medicare-RADV-Report-2018.07.pdf. This report and its underlying technical evaluation of the CMS RADV methodology was commissioned by America's Health Insurance Plans (AHIP).

measurement error would be higher." This issue is reflected in the Study, which identified wide variation in discrepancy rates for HCCs mapped from diagnoses in the sample set.

Issue #5: <u>Expansion of MA Plan Appeal Rights</u>

BCBSA appreciates the steps that CMS has taken to potentially enhance the administration of the RADV appeals process, including expansion and clarification of MA plan appeal rights.[14] In the Proposed Rule, CMS announced that it is "considering whether to explicitly expand the MA organizations' RADV appeal rights," in light of anticipated audits and recoveries under the new RADV standards.

Recommendation #5:

BCBSA supports future regulatory changes to the appeals process and HCC validation procedures that would improve the overall accuracy and fairness of the RADV audit process.

Specifically, CMS should propose the following changes in future rule-making:

a) **Increase the time available for plans to initiate RADV appeals**
b) **Allow the same set of validating evidence for appeals as is allowed in initial audits**
c) **Allow plans to use any available source to document the validity of a diagnosis code**
d) **Expand the overly restrictive hardship exception request policy**

Rationale #5: Reforms are warranted to ensure that the appeals process and HCC validation procedures are accurate and fair, especially in light of methodological and procedural changes proposed for 2020.

a. Increase the time available for plans to initiate RADV appeals.

Currently, MA plans must file a written request for an appeal within 60 days of the RADV audit report. Under the extensive changes to the RADV model proposed in this rule, MA plans would need additional time to review issues on which an appeal might be based given the increased complexities and risks. This period does not give plans sufficient time to conduct a thorough review of the audit report, determine if there are payment calculations and/or medical record issues that warrant appeal, and develop an appeal request. In view of these practical challenges, we believe that CMS should lengthen the appeals deadline to afford MA plans a reasonable amount of time to prepare and file appeals.

Similarly, the deadline governing the reconsideration stage of the appeals should be expanded to 90 days. Under the current rules, upon request for a CMS Administrator review, the hearing officer's ruling from the prior stage of appeal becomes final if the Administrator declines to review that ruling or does not make a decision within 60 days. This process does not afford the

[14] CMS, Final Rule, Medicare Program; CY 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29844, 29926 (May 23, 2014).

MA plan a meaningful opportunity to appeal a hearing officer's unfavorable decision if it is finalized due to the Administrator's inaction. Lengthening the deadline by 30 days would provide both MA plans and CMS more time to properly administer and engage in the appeals process.

b. Allow the same set of validating evidence for appeals as is allowed in initial audits.

With the announcement of the RADV audit extrapolation methodology in February 2012, CMS slightly broadened its medical records procedures to allow MA plans to submit more than one medical record to validate an audited HCC. However, this procedure has remained unduly restrictive in the audit context, and CMS continues to apply its "one best medical record" policy with respect to audit appeals. CMS should revisit this policy in light of proposed changes to the RADV methodology that substantially increase the potential repayment risks for MA plans. Notably, there is an inconsistency between permitting MA plans to submit more than one medical record during the RADV audits and forbidding the submission of multiple records on appeal. Unless this inconsistency is remedied by broadening the basis of documentation on appeal, the reviewer would obtain an incomplete picture of the clinical data that the plan initially submitted to support the HCC. To ensure the integrity and accuracy of risk adjustment payment data, RADV audit procedures—at both the audit and appeals phase—should permit MA plans to build their case for HCC validation based on all pertinent underlying medical records.

c. Allow plans to use any available source to document the validity of a diagnosis code.

The purpose of RADV audits is to ensure the integrity and accuracy of risk adjustment payment data and to recover for unsubstantiated MA plan payments. However, this purpose is undermined by current rules that forbid appealing MA plans from including HCCs, medical records or other documents beyond the audited HCC, the RADV-reviewed medical record, and any accompanying attestation. This rule imposes an arbitrary and onerous documentation standard that does not further CMS' goal of properly assessing risk adjustment data.

When a MA plan lacks a medical record documentation that supports an audited HCC, CMS should allow the plan to add any evidentiary support demonstrating that the patient has the diagnosis in question. Such additional support could be found in Medicare Part D prescription drug data, laboratory results, prior or current claims data or supplemental documentation from the patient's current treating physicians attesting to the existence of the disease. This is especially important for certain chronic conditions that may require lifelong treatment, such as Parkinson's disease, Huntington's disease, aortic atherosclerosis, Type 1 diabetes or complications from an amputation. Treating providers often fail to explicitly identify these conditions in the medical record because it may be presumed or readily apparent that the patient has the condition in question. For example, if a beneficiary with Type 1 diabetes is in the RADV audit sample, but the MA plan does not have medical record documentation from that audit time period specifically establishing the condition, the plan should be able to furnish proof in the form of other claims data and/or prescription drug records for insulin.

While we provide this recommendation within the context of appeals, BCBSA believes that MA plans should be allowed (but not required) to provide alternative and supplemental forms of

proof in both the audit and appeals stage of the RADV process to enhance CMS' ability to determine the accuracy of payment.

d. Expand the overly restrictive hardship exception request policy.

CMS should broaden the list of allowable hardship exceptions that may prevent an MAO from meeting RADV audit requirements. The list of hardship exceptions should provide accommodations for delays in obtaining medical records or attestations as a result of providers who are traveling, sick, or deceased.